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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,450

09/01/2005

Marc Donath

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EXAMINER

DANG, IAN D

ART UNIT

PAPER NUMBER

1647

NOTIFICATION DATE

DELIVERY MODE

02/04/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/517,450	Applicant(s) DONATH, MARC	
	Examiner IAN DANG	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 22-26 is/are allowed.
- 6) ☒ Claim(s) 15-17 is/are rejected.
- 7) ☒ Claim(s) 19-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 14 November 2008 has been entered in full. Claims 1-14 have been cancelled and claim 15 has been amended.

Claims 15-26 are under examination.

Rejections Withdrawn

35 USC § 112, First paragraph (Enablement)

Applicant's response and arguments filed on 11/14/2008 have overcome the rejection of claims 15-21 under 35 USC 112, First paragraph (Enablement). Applicants have provided the publication by Sauter et al. describing test results indicating that Kineret is able to protect from diabetes progression induced by a high-fat diet (see page 5 of the response). In addition, Applicants have amended claim 15 with the limitation "in a mammal predisposed to type 2 diabetes". The rejection of claims 15-21 under 35 USC 112, First paragraph (Enablement) has been withdrawn.

35 USC § 102

Applicant's response and arguments filed on 11/14/2008 have overcome the rejection of claims 15-16 under 35 USC 102(b). Applicants have amended claim 15 with the limitation "in a mammal predisposed to type 2 diabetes" that is not disclosed in the reference by Thompson et al. (US Patent 6,159,460). The rejection of claims 15-16 under 35 USC 102(b) has been withdrawn.

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Rejection Maintained

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Boone et al. (US Patent No. 6,294,170, filed August 07, 1998) in view of Thompson et al. (US Patent No. 6,159,460, filed August 18, 1994).

At page 6 of the response, Applicants argue that the term "insulin diabetes" used in the two cited references would be understood by those skilled in the art to actually refer to type-1 diabetes, and would not be understood to refer to type-2 diabetes. Type-1 diabetes is often referred to as "insulin-dependent diabetes" and is understood to be an autoimmune disease that results in the permanent destruction of the insulin-producing beta cells of the pancreas. In complete contrast, type-2 diabetes is often referred to as "non-insulin-dependent diabetes mellitus" (or NIDDM). It is therefore submitted that the Examiner's underlying assumption that the term "insulin diabetes" implicitly also includes type-2 diabetes is actually self contradictory and represents a fundamental misunderstanding of diabetes.

In addition, at the time of filing of the present application those skilled in the art had identified a large number of different types of diabetes, actually 11 different main types of diabetes and including at least 50 different subtypes. Applicant argues that any reference by

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Boone and Thompson to "insulin diabetes" would have been understood to be a reference to type-1 diabetes and not a generic reference to type-1, type-2 and any of the other 11 main types of diabetes or 50 different subtypes, nor to a generic term to encompass type-1 and type-2 diabetes.

Applicants' arguments have been considered but are not found persuasive. Although Applicants argue that the term "insulin diabetes" in the reference of Boone et al. refers to type-1 diabetes and not type-2 diabetes, or any of the other 11 main types of diabetes or 50 different subtypes, Applicants have not provided any evidence for such a definition. In the absence of evidence to the contrary, the examiner's interpretation that the recitation of "insulin diabetes" in the reference by Boone et al. corresponding to type 2 diabetes is maintained. As disclosed in the previous office action (mailed 05/14/2008), it would be obvious that the treatment of IL-1 mediated disease with IL-1RA would include type 2 diabetes.

Please note that a declaration by Applicant disclosing the term "insulin diabetes" corresponds to "type-1 diabetes would overcome the rejection.

Conclusion

Claims 15-17 are not allowed. Claims 18-21 are objected as they are dependent on claims 15-17. Claims 22-26 are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
January 28, 2009

/Robert Landsman/
Primary Examiner, Art Unit 1647